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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,477	11/13/2000	Isabelle Preuilh	2365-23	4547

7590

11/25/2003

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EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/25/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/709,477

Applicant(s)

PREUILH ET AL.

Examiner

Lauren Q Wells

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-33,35-48 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-33,35-48 and 50-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 32-33, 35-48, 50-61 are pending. The Amendment filed 10/8/03, Paper No. 17, amended claims 31, 40 and 50 and cancelled claim 49.

Applicant's arguments and amendment filed 10/8/03, Paper No. 17, are sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 37-48, 50-51, 55, 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Andrews et al. (5,378,731) and in view of The Handbook of Cosmetic Science and Technology.

The instant invention is directed toward a composition comprising, in an aqueous medium, an active principle selected from a corticoid or a retinoid, an anionic surfactant, an amphoteric surfactant, and 0.1-25% of a propenetrating agent.

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative, and other ingredients, wherein the detergent can be a combination of sodium lauryl sulfate and coamidopropyl betaine. The

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reference fails to teach propenetrating agents, the combination of anionic and amphoteric surfactant, and fails to explicitly state the pH. See Col. 1, line 5-Col. 6, line 35.

Andrews et al. teach medicated shampoos. Propylene glycol in an amount of 0.1-5% is taught as a viscosity modifier that serves to alter the viscosity of the composition so as to achieve a desired viscosity. It is taught that a thicker more viscous shampoo may be desired for those having short hair, while those with longer hair usually prefer a less viscous shampoo. See Col. 6, lines 15-39. The shampoos are exemplified as having a pH from 3.6-3.8, see Col. 11, lines 9-44.

The Handbook of Cosmetic Science and Technology teaches that amphoteric surfactants provide foam stabilization in combination with the ability to mitigate irritancy of other materials, such as primary surfactants, and, in some cases, will modify product viscosity. They are taught as compatible with anionic surfactants, wherein anionic surfactants are taught as primary surfactants. See pages 220-224.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add 0.1-5% propylene glycol, as taught by Andrews et al., to the composition of Cameron because of the expectation of achieving a composition in which the viscosity can be altered so as to achieve a shampoo that is preferable to those with long hair and those with short hair.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the pH of the shampoos of Cameron as 3.6-3.8, as taught by Andrews et al. because of the expectation of achieving a cosmetically acceptable formulation that is safe for application to the hair and scalp.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Cameron comprising both the anionic and amphoteric surfactants because of the expectation of achieving a composition that is more stable and decreases irritation, as taught by the Handbook of Cosmetic Science and Technology.

While the ratio of anionic to amphoteric surfactant is not taught, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

The Examiner respectfully points out that the recitation “Foaming” and “for washing and treating the hair and/or scalp” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 33, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Andrews et al. and in view of the Handbook of Cosmetic Science and Technology as applied to claims 31, 32, 37-48, 50-51, 55, 57-61 above, and further in view of Kligman (5,998,395).

Cameron, Andrews et al, and the Handbook of Cosmetic Science and Technology are applied as discussed above. The reference does not teach preferred corticoids and retinoids.

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Kligman teach methods of treating inflammatory dermatosis. Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition and the retinoid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments, or liquids. Further examples of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. The retinoids can be natural or synthetic. See Col. 1, line 19-Col. 12, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the corticoids and retinoids taught by Kligman into the composition of the combined references because of the expectation of achieving a composition that exhibits a synergistic effect in treating chronic dermatoses, such as seborrheic dermatitis, atopic dermatitis, contact dermatitis, psoriasis, and others, and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Andrews et al. and in view of the Handbook of Cosmetic Science and Technology as applied to claims 31, 32, 37-48, 50-51, 55, 57-61 above, and further in view of Cauwet et al. (5,661,118).

Cameron, Andrews et al., and the Handbook of Cosmetic Science and Technology are applied as discussed above. The reference does not teach cationic polymers and ceramides.

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Cauwet et al. teach hair and skin washing and treatment compositions based on ceramide and/or glycoceramide and cationic polymers. The combination of cationic polymer and ceramic and/or glycoceramide provides synergistic disentangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guar hydroxypropyltrimonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition. See Col. 13, line 1-Col. 20, line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the cationic polymer and ceramide taught by Cauwet et al. to the composition of the combined references because of the expectation of achieving a shampoo composition with synergistic disentangling effects.

### ***Response to Arguments***

Regarding Cameron, Applicant argues, "The examples only contain an anionic surfactant". This argument is not persuasive. The Examiner respectfully points out that this is a 103-obviouness rejection and not a 102-anticipation rejection, wherein it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983).

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Applicant argues, “there was no motivation for one of ordinary skill in the art, who wished to solve the problem of the present application, to combine Cameron et al. relating to a stable medicated shampoo composition with an improved shelf life, with Preuilh et al. relating to the stability of emulsions comprising high content of propenetrating glycol and The Handbook of Cosmetic Science and Technology which teaches the possible combination of amphoteric and anionic surfactants”. This argument is not persuasive. First, the Examiner respectfully points out that Preuilh et al. is no longer relied upon as a reference. Second, the Examiner respectfully points out that this argument is not commensurate in scope with the instant claims, as the instant claims are directed toward a product and not a problem to be solved.

Applicant argues, “None of the two remaining documents, namely Preuilh et al. and The Handbook of Cosmetic Science and Technology, indicate or suggest that the colloidal sulphur can be removed from the composition of Cameron et al. and that a stable composition could be obtained also with the combination as claimed, for example in claim 31”. This argument is not persuasive. The Examiner respectfully points out that Applicant’s open-ended language in the instant claims, the term “comprising”, does not exclude any ingredients from its composition. Thus, the rejection need not remove colloidal sulphur from the composition of Cameron et al. to read on the instant claims.

Applicant argues, “The problem raised in Kligman relates to control and to clear more effectively the inflammatory dermatosis. This problem has been solved by Kligman by using the particular combination corticosteroid/retinoid”. This argument is not persuasive. The Examiner respectfully points out that Kligman is merely relied upon to teach specific corticoids and retinoids that can be added to the composition of Cameron for the purpose of treating



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inflammatory dermatosis of the scalp. One of skill would be motivated to add the specific corticosteroids and retinoids taught by Kligman to the composition of Cameron because of the expectation of effectively treating flaking, scaling, dandruff, psoriasis, eczema, seborrhea, and other inflammatory dermatosis of the scalp.

Applicant argues, "The problem raised in the present application does not consist in using new active principle as taught by Kligman et al., but consists in improving the penetration of the active principle while improving the characteristics of volume and compactness of the foam and allowing the hair to exhibit good cosmetic properties such as softness, non-greasiness and manageability". This argument is not persuasive, as it is not commensurate in scope with the instant claims.

Applicant argues, "Cauwet does not teach the combination of anionic and amphoteric surfactants with active principles and propenetrating agents, as present claimed". This argument is not persuasive, as Cauwet is merely relied upon to teach cationic polymers and ceramides.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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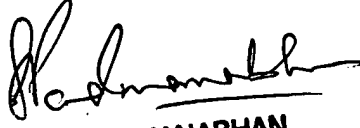
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER

11/24/03